REMARKS

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the August 15, 2006 Office Action.

Claims 9 to 15, 21, 22, 23, 25, 27, and 29 to 36 are pending in this application. The Examiner rejected Claims 9 - 15, 21 - 23, 25, 27, and 29 - 36. In particular, the Examiner rejected Claims 9 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,800,409 ("the Bruce patent"). The Examiner further rejected Claims 13, 21-23, 25, 31, 33, and 34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,800,409 ("the Bruce patent"). The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Bruce ('409), in view U.S. Patent Application Publication Number 2002/0161353 (the Kortelling application). The Examiner rejected Claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Bruce ('409), in view U.S. Patent Number 6,669.708 (the Nissenbaum et al. patent). The Examiner rejected Claims 15 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Bruce ('409), in view U.S. Patent Number 5,509,909 (the Moy patent). The Examiner rejected Claims 29, 30, 35, and 36 under 35 U.S.C. § 103(a) as being unpatentable over Bruce ('409), in view U.S. Patent Number 5,370,899 (the Conway et al. patent). The Examiner rejected Claim 32 under 35 U.S.C. § 103(a) as being unpatentable over Bruce ('409), in view U.S. Patent Number 6,319.246 (the de la Torre et al. patent). In view of the following discussion, reconsideration of the application is respectfully requested.

REJECTION OF CLAIMS 9 and 10 UNDER 35 U.S.C. § 102(b)

The Examiner rejected Claims 9 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,800,409 ("the Bruce '409 patent").

Claim 9

The Bruce '409 patent appears to disclose a valve housing 26 that has a removable valving mechanism 44 as evidenced by the fact that the valving mechanism 44 is missing from Figures 1, 2, 3, and 4. The Bruce '409 patent appears to disclose a valving mechanism 44 that must be manually opened to permit the passage of the

trocar 54 through the central lumen 38 of the cannula 10 and manually closed once the trocar is removed in order to seal the valve orifice. The Bruce '409 patent appears to disclose a cannula 10 that is inserted substantially straight. Removal of the trocar 54 appears to permit flexibility of the cannula so that it can bend with the knee following placement. The downward force on the distal end is generated laterally to the cannula 10 by manual force of a hand, a condition that can only be generated at the distal end of the cannula and with the distal end of the cannula outside of the body. The trocar 54 appears to be generally straight and renders the device substantially straight during insertion. The Bruce '409 patent appears to teach an instrument for cannulation of a suprapatellar or knee pouch which has no requirements for maintaining an air-tight seal against a loss of vacuum. In contrast, the loss of an air tight seal would imperil the life of a chest tube patient.

In summary, there appears to be no suggestion or disclosure of any steering mechanism, nor is there any motivation for steering the device into the knee or other arthroscopic cavity, as taught by Bruce '409. There appears to be no disclosure or suggestion of articulation of the distal end of the cannula controlled from the proximal end of the cannula. The Bruce '409 patent appears not to disclose a tube adapted to drain the chest cavity. There appears to be no motivation or suggestion to use the device in situations other than those of arthroscopic surgery. There appears to be no teaching, disclosure, motivation or suggestion for a valve that permits trocar passage and then automatically closes down once the trocar is removed.

Because the reference cited by the Examiner does not appear to disclose, teach or suggest a method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising inserting a tapered tip of a flexible trocar and a distal end of an axially elongate tube into an incision into a thoracic cavity of a mammalian patient, wherein the flexible trocar is pre-inserted through a drainage lumen of a bidirectional, non-removable, pressure-operated valve attached to a proximal end of the axially elongate tube and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube, selectively bending a region near the distal tip of the axially elongate tube while advancing the axially elongate tube into the thoracic cavity, wherein the bending steers the axially elongate

tube into the thoracic cavity during insertion, removing the flexible trocar through the valve from the drainage lumen of the axially elongate tube and the drainage lumen of the valve, and selectively opening or closing the valve to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube, applicants assert that Claim 9 is not anticipated by Bruce '409. Applicants therefore respectfully submit that Claim 9 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 9.

Claim 10

Claim 10, which depends from Claim 9, is believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

REJECTION OF CLAIMS 13, 21-23, 25, 31 and 34 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 9 and 10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,800,409 ("the Bruce '409 patent").

Claim 13

Claim 13, which depends from Claim 9, is believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

Claim 21

The Bruce '409 patent appears to disclose a valve housing 26 that has a removable valving mechanism 44 as evidenced by the fact that the valving mechanism 44 is missing from Figures 1, 2, 3, and 4. The Bruce '409 patent appears to disclose a valving mechanism 44 that must be manually opened to permit the passage of the trocar 54 through the central lumen 38 of the cannula 10 and manually closed once the trocar is removed in order to seal the valve orifice. The Bruce '409 patent appears to disclose a cannula 10 that is inserted straight. Removal of the trocar 54 appears to permit flexibility of the cannula so that it can bend with the knee following placement.

The downward force on the distal end is generated laterally to the cannula 10 by manual force of a hand, a condition that can only be generated at the distal end of the cannula and with the distal end of the cannula outside of the body. The trocar 54 appears to be generally straight and renders the device substantially straight during insertion. The Bruce '409 patent appears to teach an instrument for cannulation of a suprapatellar or knee pouch which has no requirements for maintaining an air-tight seal against a loss of vacuum. In contrast, the loss of an air tight seal could imperil the life of a chest tube patient since it could result in a pneumothorax and inability to breathe.

In summary, there appears to be no suggestion or disclosure of any steering mechanism, nor is there any motivation for steering the device into the knee or other arthroscopic cavity, as taught by Bruce '409. There appears to be no disclosure or suggestion of articulation of the distal end of the cannula controlled from the proximal end of the cannula. The Bruce '409 patent appears not to disclose or teach a tube adapted to drain the chest cavity. There appears to be no motivation or suggestion to use the device in situations other than those of arthroscopic surgery. There appears to be no teaching, disclosure, motivation or suggestion for a valve that permits trocar passage and then automatically closes down once the trocar is removed. There appears to be no teaching, disclosure, motivation, or suggestion for a guidewire lumen in either the cannula 10 or the trocar 54. Arthroscopic surgery generally does not anticipate use of a guidewire so there is no provision for a guidewire to be used on the device of Bruce '409. A guidewire channel in a cannula is just barely larger than the guidewire itself, so that the cannula is able to flex and be forced or guided along the path of the already placed guidewire. The trocar 54 appears not to include any type of lumen, guidewire or otherwise. The trocar 54 appears to be rigid or slightly flexible but does not appear to be flexible to the extent necessary to track a guidewire around bends and turns.

Because the reference cited by the Examiner does not appear to disclose, teach or suggest a method of draining of fluid, air and contaminants from a patient's thoracic cavity comprising inserting a hollow needle into an incision into the thoracic cavity of a patient, inserting a guidewire through the hollow needle into the thoracic cavity, removing the hollow needle after inserting the guidewire, pre-attaching a non-

removable, bidirectional valve, further comprising a drainage lumen and a valve control lumen, to the proximal end of an axially elongate tube, wherein the axially elongate tube comprises a proximal end, a distal end, and a drainage lumen extending substantially the axial length of the axially elongate tube, inserting a flexible trocar comprising a tapered distal tip, and a guidewire lumen within the flexible trocar, extending the length of the flexible trocar, through a drainage lumen of the valve, into the proximal end of the axially elongate tube and into the drainage lumen of the axially elongate tube until the tapered distal tip extends beyond the distal end of the axially elongate tube, inserting a distal end of the axially elongate tube, comprising the pre-inserted flexible trocar and pre-attached, bidirectional, pressure-operated valve, over the guidewire and through the incision into the thoracic cavity of the patient, wherein the distal end of the axially elongate tube is advanced into the thoracic cavity of the patient, removing the flexible trocar from the drainage lumen of the axially elongate tube and from the drainage lumen of the valve, selectively opening or closing the drainage lumen of the valve, to control the influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube, and removing the guidewire after inserting the axially elongate tube, applicants assert that Claim 21 is not obvious in view Bruce '409. Applicants therefore respectfully submits that Claim 21 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 21.

Claims 22-33, 25, 31, and 33

Claims 22-23, 25, 31, and 33, which depend from Claim 21, are believed to be patentable for the same reasons articulated above with respect to Claim 21, and because of the additional features recited therein.

Claim 34

The Bruce '409 patent appears to disclose a valve housing 26 that has a removable valving mechanism 44 as evidenced by the fact that the valving mechanism 44 is missing from Figures 1, 2, 3, and 4. The Bruce '409 patent appears to disclose a valving mechanism 44 that must be manually opened to permit the passage of the

trocar 54 through the central lumen 38 of the cannula 10 and manually closed once the trocar is removed in order to seal the valve orifice. The Bruce '409 patent appears to disclose a cannula 10 that is inserted straight. Removal of the trocar 54 appears to permit flexibility of the cannula so that it can bend with the knee following placement. The downward force on the distal end is generated laterally to the cannula 10 by manual force of a hand, a condition that can only be generated at the distal end of the cannula and with the distal end of the cannula outside of the body. The trocar 54 appears to be generally straight and renders the device substantially straight during insertion. The Bruce '409 patent appears to teach an instrument for cannulation of a suprapatellar or knee pouch which has no requirements for maintaining an air-tight seal against a loss of vacuum. The loss of an air tight seal could result in a pneumothorax in a chest tube patjent the result of which could be the inability to breathe.

In summary, there appears to be no suggestion or disclosure of any steering mechanism, nor is there any motivation for steering the device into the knee or other arthroscopic cavity, as taught by Bruce '409. There appears to be no disclosure or suggestion of articulation of the distal end of the cannula controlled from the proximal end of the cannula. The Bruce '409 patent appears not to disclose or teach a tube adapted to drain the chest cavity. There appears to be no motivation or suggestion to use the device in situations other than those of arthroscopic surgery. There appears to be no teaching, disclosure, motivation or suggestion for a valve that permits trocar passage and then automatically closes down once the trocar is removed.

Because the reference cited by the Examiner does not appear to disclose, teach or suggest a method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising inserting a chest drainage apparatus into a thoracic cavity of a mammalian patient, wherein the chest drainage apparatus comprises an axially elongate tube with a pre-inserted flexible trocar having a tapered distal tip, further wherein the flexible trocar is pre-inserted through a non-removable, bidirectional, pressure-operated valve, attached to a proximal end of the axially elongate tube, and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube, advancing the chest drainage apparatus to its target location within the thoracic cavity, removing the flexible trocar from the drainage lumen

of the valve and the axially elongate tube, and selectively opening or closing the valve to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube, applicants assert that Claim 34 is not obvious in view Bruce '409. Applicants therefore respectfully submits that Claim 34 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 34.

REJECTION OF CLAIMS 11 and 14 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 11 and 14 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,800,409 ("the Bruce '409 patent") in view of Kortelling (U.S. Patent Publication No. 2002/0161353).

Claims 11 and 14

Claims 11 and 14, which depend from Claim 9, are believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

REJECTION OF CLAIM 12 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claim 12 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,669,708 ("the Nissenbaum '708 patent").

Claim 12

Claim 12, which depends from Claim 9, is believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

REJECTION OF CLAIMS 15 and 27 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 15 and 27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,800,409 ("the Bruce '409 patent") in view of U.S. Patent No. 5,509,909 (the Moy '909 patent).

Claims 15 and 27

Claim 15, which depends from Claim 9 and Claim 27, which depends from Claim 21, are believed to be patentable for the same reasons articulated above with respect to Claims 9 and 21, and because of the additional features recited therein.

REJECTION OF CLAIMS 29, 30, 35 and 36 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 29, 30, 35 and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,800,409 ("the Bruce '409 patent") in view of U.S. Patent No. 5,370,899 (the Conway at al. '899 patent).

Claims 29, 30, 35 and 36

Claims 29, 30, 35, and 36, which depend from Claim 21, are believed to be patentable for the same reasons articulated above with respect to Claim 21, and because of the additional features recited therein.

REJECTION OF CLAIM 32 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claim 32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,319,246 (the de la Torre et al. '246 patent).

Claim 32

Claim 32, which depends from Claim 21, is believed to be patentable for the same reasons articulated above with respect to Claim 21, and because of the additional features recited therein.

CONCLUSION

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

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